

Whitehall-Robins
Five Giralda Farms
Madison, NJ 07940-0871
Telephone (973) 660-5500
Website address: http://healthfront.com

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June 25, 1999

Caltrate® + D

6/29/49

Notification of Statements on Dietary Supplement Labels

Elizabeth A. Yetley, Ph.D., R.D., Director Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C Street, SW Washington, D.C. 20204

Dear Dr. Yetley:

Reference is made to Caltrate® + D, marketed by Whitehall-Robins Healthcare ("Whitehall-Robins"), ad'ivision of American Home Products Corporation.

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, as codified in 21 U.S.C. §343(r)(6), notification is submitted for structure/function statements made on the following dietary supplement product.

Product Name: Caltrate + D

Ingredients: Calcium Carbonate, Vitamin D

Company Name/ Whitehall-Robins Healthcare Five Giralda Farms

Madison, New Jersey 07940

Statement on the Label:

Side Panel of Label

Each tablet provides more calcium for your bones than any leading brand.*

LET 3887

In accord with 21 CFR \$101.93, the disclaimer statement is **bolded** and boxed on the panel of the carton where structure/function claim appears.

Additionally, the back panel of the label contains the health claim "may reduce the risk of osteoporosis" with all required information for use of such claim.

The undersigned certifies that the information contained in this notice is complete and accurate, and that Whitehall-Robins has substantiation that the statement made is truthful and not misleading.

As required, the original and two copies of this notification are enclosed. If you have any questions regarding this information, please contact the undersigned at (973) 660-575 1.

Sincerely,

WHITEHALL-ROBINS HEALTHCARE

Eleanor F. Barbo Senior Director

Regulatory Affairs